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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Com	plete if Known
Application Number	09/226,044
Filing Date	January 5, 1999
First Named Inventor	Allan S. Hoffman
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	UWS 102 (OTT 2219-2744 DL)

			U.S. PATENT DOCU	MENTS	
xaminer Initials*	Cite No. ¹	US Patent Documen Number Kind Coc (if know	of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1 //		4,657,543	Langer, et al.	04-14-1997	
षर		5,501,584	Yamamoto, et al.	03-26-1996	
		5,521,291	Curiel, et al.	05-28-1996	
		5,547,932	Curiel, et al.	09-20-1996	
\Box		5,599,908	Raso	02-04-1997	
	,	5,603,931	Raso	02-18-1997	·
\mathcal{A}	,	5,656,609	Wu, et al.	09-12-1997	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T°
,		Office.3	Number⁴	Kind Code ⁵ (if known)				
		WO/	96/40958	A1	Baylor College Medicine	12-19-1996	•	1
		WO	97/04832	A1	Mass. Inst. of Tech.	02-13-1997		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	09/226,044	SEP 1 4 1999
				Filing Date	January 5, 1999	CEAU 108
				First Named Inventor	Allan S. Hoffman	4 TRAUE
				Group Art Unit	1615	
				Examiner Name		
Sheet	2	of	4	Attorney Docket Number	UWS 102 (OTT 2219	9-2744 DL)

Examiner's 1	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	Т
Initials*	No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
		ABELEV, "Alpha-fetoprotein in ontogenesis and its association with malignant tumors," Adv. Cancer Res. 14:295-350 (1971).	
		ANDERSON, et al., "Enhanced in vitro tumor cell retention and internalization of antibody derivatized with synthetic peptides," <i>Bioconjug Chem.</i> 4(1):10-8 (1993).	
		BUSCHLE, et al., "Receptor-mediated gene transfer into human T lymphocytes via binding of DNA/CD3 antibody particles to the CD3 T cell receptor complex," <i>Hum Gene Ther.</i> 6(6):753-61 (1995).	
		CHOI, et al. "Lactose-poly(ethylene glycol)-grafted poly-L-lysine as hepatoma cell-tapgeted gene carrier," <i>Bioconjug Chem.</i> 9(6):708-18 (1998).	
		DONBROW, Ed., Microcapsules and Nanoparticles in Medicine and Pharmacy CRC Press:Boca Raton, 1992.	
		GEISOW, "Fluorescein conjugates as indicators of subcellular pH. A critical evaluation," Experimental Cell Research 150:29-35 (1984)	
		GOLD, et al., "Specific carcinoembryonic antigens of the human digestive system," J. Exp. Med. 122:467-481 (1965).	
		GUY, "Current status and future prospects of transdermal drug delivery," Pharm Res. 13(12):1765-9 (1996).	
		HAENSLER, et al., "Polyamidoamine cascade polymers mediate efficient transfection of cells in culture," <i>Bioconjugate Chem.</i> 4: 372-379 (1993).	
$\left\langle \cdot \right\rangle$		HUGHES, et al., "Evaluation of adjuvants that enhance the effectiveness of antisense oligodeoxynucleotides," <i>Pharm Res.</i> 13(3):404-10 (1996).	

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				Filing Date	January 5, 1999	
				First Named Inventor	Allan S. Hoffman	
				Group Art Unit	1615	
				Examiner Name		
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(M)		KIRCHEIS, et al., "Coupling of cell-binding ligands to polyethylenimine for targeted gene delivery," <i>Gene Ther.</i> 4(5):409-18 (1997).							
		KOST, et al., "Responsive polymer systems for controlled delivery of therapeutics," TIBTECH 10:127-131 (1992).							
	-	PAWLAK, et al., "Template-assembled melittin: structural and functional characterization of a designed, synthetic channel-forming protein," <i>Protein Science</i> 3:1788-1805 (1994).							
		PERALES, et al., "An evaluation of receptor-mediated gene transfer using synthetic DNA-ligand complexes," Eur J Biochem. 226(2):255-66 (1994).							
		PLANK, et al., "The influence of endosome-disruptive peptides on gene transfer using synthetic virus-like gene transfer systems," <i>J. Biol. Chem</i> 269: 12918-12924 (1994).							
		PRAUSNITZ, et al., "Electroporation of mammalian skin: a mechanism to enhance transdermal drug delivery," Proc Natl Acad Sci U S A. 90(22):10504-8 (1993).	_						
		PRAUSNITZ, et al., "Reversible skin permeabilization for transdermal delivery of macromolecules," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 14:455-483 (1997).	_						
		PRAUSNITZ, et al., "Transdermal delivery of heparin by skin electroporation," Biotechnology (N Y). 13(11):1205-9 (1995).							
		PRESS, et al., "Endocytosis and degradation of murine anti-human CD3 monoclonal antibodies by normal and malignant T-lymphocytes," Cancer Research 48:2249-2257 (1988).							
		ROSS, et al., "Gene therapy in the United States: a five-year status report," Hum Gene Ther. 7(14):1781-90 (1996).	_						
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		(use	as many si	nees as necessary)	Filing Date	January 5, 1999		
					First Named Inventor	Allan S. Hoffman		
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1		THOM	IAS, et al	., "Polyelectrolyte-sensitiz	zed phospholipid vesicles," Acc. Ci	hem. Res. 25: 336-342 (1992).		
				., "Membrane solubilizatio rnal 67:1101-1106 (1994		surface activity and membrane binding,"		
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	THOMAS, et al., "Polyelectrolyte-sensitized phospholipid vesicles," Acc. Chem. Res. 25: 336-342 (1992).	
	THOMAS, et al., "Membrane solubilization by a hydrophobic polyelectrolyte: surface activity and membrane binding," Biophysical Journal 67:1101-1106 (1994).	
	TOLSTIKOV, et al., "Influence of endosome-destabilizing peptides on efficacy of anti-HIV immunotoxins," <i>Bioconjug Chem.</i> 8(1):38-43 (1997).	
	VINOGRADOV, et al., "Self-assembly of polyamine-poly(ethylene glycol) copolymers with phosphorothioate oligonucleotides," <i>Bioconjug Chem.</i> 9(6):805-12 (1998).	
	WANG, et al., "Delivery of antisense oligonucleotides using HPMA polymer: synthesis of A thiol polymer and its conjugation to water-soluble molecules," <i>Bioconjug Chem.</i> 9(6):749-57 (1998).	
	WEAVER, et al., "Electroporation: A general phenomenon for manipulating cells and tissues," <i>J Cell Biochem</i> . 51(4):426-35 (1993).	
	WILDER, et al., "Radioimmunotherapy: recent results and future directions," J. Clin. Oncol. 14:1383-1400 (1996).	
		THOMAS, et al., "Membrane solubilization by a hydrophobic polyelectrolyte: surface activity and membrane binding," Biophysical Journal 67:1101-1106 (1994). TOLSTIKOV, et al., "Influence of endosome-destabilizing peptides on efficacy of anti-HIV immunotoxins," Bioconjug Chem. 8(1):38-43 (1997). VINOGRADOV, et al., "Self-assembly of polyamine-poly(ethylene glycol) copolymers with phosphorothioate oligonucleotides," Bioconjug Chem. 9(6):805-12 (1998). WANG, et al., "Delivery of antisense oligonucleotides using HPMA polymer: synthesis of A thiol polymer and its conjugation to water-soluble molecules," Bioconjug Chem. 9(6):749-57 (1998). WEAVER, et al., "Electroporation: A general phenomenon for manipulating cells and tissues," J Cell Biochem. 51(4):426-35 (1993). WILDER, et al., "Radioimmunotherapy: recent results and future directions," J. Clin. Oncol. 14:1383-1400 (1996).

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